REMARKS/ARGUMENTS

Applicants have fully considered the Office Action mailed May 4, 2005. Applicants request reconsideration of the application.

A. The Office Action.

In the office action mailed May 4, 2005, the Examiner withdrew claim 1 from further consideration as being drawn to a non-elected invention, and rejected claims 23-70. Applicants cancel claim 1, which is drawn to a non-elected invention. Claims 23-70 remain pending.

B. Priority Claim.

In the Office Action, the Examiner acknowledged that Applicants claimed foreign priority from GB 9610944.2 or GB 9705498.5. The Examiner requested that certified copies of those applications be filed as required by 35 U.S.C. §119(b).

The present application is a divisional application of U.S. Serial No. 09/194,267 (now U.S. Patent No. 6,756,054), which was a national phase application based upon PCT Application No. PCT/GB97/01426. The '267 application entered the U.S. national phase by the normal national processing route under the PCT rules. As such, Applicants submitted certified copies of GB 9610944.2 and GB 9705498.5 with the international bureau. A copy of a communication received from the international bureau discloses the receipt of the two above-mentioned priority documents (Attachment A).

Therefore, Applicants respectfully submit that since the present application is a divisional application of a national phase application based upon a PCT application where the two priority documents have already been filed, Applicants are not required to submit certified copies of the two priority documents.

C. The Examiner's Concerns Regarding Claim 68 Have Been Remedied.

The Examiner objected to claim 68 for an informality. Claim 68 is amended herein to delete "necleotide" and insert the word "nucleotide" in its place. Applicants submit that this change remedies the Examiner's concerns. Applicants request that the objection be withdrawn.

D. The Specification Complies With the Enablement Requirement.

The Examiner rejected claims 23-70 under 35 U.S.C. §112, first paragraph, as

failing to comply with the enablement requirement. Specifically, the Examiner contends that the art is unpredictable and that the specification does not include a specific and detailed description of how to effectively practice the claimed methods and would require undue experimentation to practice the claimed methods. Applicants traverse this rejection.

Applicants submit that the specification as filed includes an enabling disclosure of a method for treating a genetic disorder, or condition, or disease in a patient. The claims are directed to methods for treating a genetic disorder or condition or disease in a patient that include administering various DC-Chol polyamine analogs. The specification discloses procedures for making the DC-Chol polyamine analogs on pages 20-24. Further, "the ability of cationic liposomes containing the different DC-Chol polyamine analogs to mediate gene delivery was analyzed both *in vitro* and *in vivo*." (Specification, page 18, lines 27-28.) The specification discloses that cationic liposomes were formulated and cationic liposome/plasmid DNA complexes were prepared by adding diluted cationic liposome suspensions into equal volumes of aqueous plasma DNA solutions. (Specification, page 18, lines 28-32, through page 19, line 1.) "*In vitro* studies were then performed with immortalised cystic fibrosis airway epithelial (CFT1) cells followed by *in vivo* studies in which cationic liposome/plasmid DNA complexes were instilled intranasally into the lungs of female BALB/c mice." (Page 19, lines 2-5.) The *in vitro* results are shown in Figure 24 (page 19, line 10), and the *in vivo* results are shown in Figure 25 (page 19, line 18). *In vitro* and *in vivo* testing procedures are discussed at pages 24-25, and detailed discussions of the results are given on pages 19-20 and 24-27.

Thus, the specification provides working examples that demonstrate that the methods are effective for treating a genetic disorder, or condition, or disease in a patient. Further, the examples include *in vivo* studies, which the Examiner highlighted as important to consider whether a gene therapy method is successful. Consequently, the specification provides a sufficient detailed description to enable a person skilled in the art to practice the claimed methods without the need for undue experimentation. Applicants request that the rejection of the claims under 35 U.S.C. §112, first paragraph, be withdrawn.

E. The Examiner's Concerns Under 35 U.S.C. §112, Second Paragraph, Have Been Remedied.

The Examiner rejected claims 22-70 under 35 U.S.C. §112, second paragraph. In particular, the Examiner expressed concern about the term "associated with." Applicants traverse this rejection.

Applicants first note that the phrase "associated with" only appears in claims 33, 35, 36, 54, 67, and 68, and respectfully submit that the rejection should only apply to claims 33, 35-44, 54-64, 67 and 68.

Applicants delete the phrase "associated with" from claims 33, 35, 36, 54, 67, and 68. Applicants submit that removing this phrase from those claims remedies the Examiner's concerns under 35 U.S.C. §112, second paragraph. Applicants request that the rejection be withdrawn.

F. The Claims Are Patentable Over the References to Boutin, et al.

The Examiner rejected claims 23-70 under 35 U.S.C. §102(b) as being anticipated by WO 96/10038 to Boutin or in the alternative under 35 U.S.C. §102(a), and also rejected these claims under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,837,533 to Boutin. Applicants traverse these rejections.

Applicants note that WO 96/10038 is a PCT application claiming priority from U.S. Patent Application No. 314,060, which issued as the '533 patent. That is, WO 96/10038 and the '533 patent are equivalent, and Applicants will address the rejections based on these references together.

The Boutin references fail to teach each and every feature recited in the claims and fail to anticipate the claims. As the Examiner notes, the present application relates to a method of treating a genetic disorder comprising administering a particular compound, namely, a DC-Chol polyamine analog. The claims recite that an analog compound includes a straight chain polyamine wherein two or more of the amine groups of the polyamine are separated by an ethylene group. The Examiner only contends that Boutin teaches a transfer moiety comprising one or more cationic polyamine components bound to a nucleic acid composition in one or more endosome membrane disrupting promoting components attached to at least one nitrogen atom of at least one said polyamine component. Boutin, however, fails to explicitly disclose the feature of two or more amine groups of a polyamine group being separated by an

ethylene group (-CH_2CH_2-). Because Boutin fails to teach this feature, Boutin fails to anticipate claims 23-70.

Applicants note that WO 96/10038 was discussed in great deal during the prosecution of U.S. Application No. 09/194,267 (now issued U.S. Patent No. 6,756,054), which is the parent application to this application. The result of that prosecution, which included a personal interview between the previous Examiner, the Examiner's supervisor, Brian Bembenick (an attorney formerly with the law firm representing the Applicants in the present matter), David Alcock (the applicants' attorney in Great Britain), and inventor Professor Andrew Miller, was the grant of the application over the disclosure of WO 96/10038 (and by implication its U.S. equivalent, U.S. Patent No. 5,837,533). Thus, the U.S. Patent Office, in their examination of U.S. Patent No. 6,756,054, has determined that claims to compounds of the structure recited in the present claims are both novel and unobvious over the Boutin, et al. references. Therefore, the present claims for a method for treating a genetic disorder, or condition, or disease in a patient, which comprises administering the novel compounds of the '054 patent, are also novel and non-obvious at least for the reasons that the compounds themselves are novel and non-obvious.

In view of the foregoing, Applicants respectfully request that the rejection of claims 23-70 in view of the Boutin, et al. references be withdrawn.

CONCLUSION

For the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 23-70) are now in condition for allowance.

Respectfully submitted,

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Date: September 1, 2005

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CERTIFICATE OF MAILING

I certify that this Amendment Transmittal and accompanying documents are being deposited with the United States Postal Service on the date indicated below and is addressed to Mail Stop – Amendment, Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: September 2, 2005	Signature: Trenia Stewart
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PATENT COOPERATION TREATY

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NOTIFICATION CONCERNING SUBMISSION OF PRIORITY DOCUMENTS

(PCT Administrative Instructions, Section 411)

Date of mailing (day/month/year)	
24 June 1997 (24.06.97)	
Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
PCT 393 1 CTH	

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/GB97/01426	23 May 1997 (23.05.97)	24 May 1996 (24.05.96)

Applicant

IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY AND MEDICINE et al

The applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to the following application(s):

Priority application No:	Priority date:	Priority country:	Date of receipt of priority document:
9705498.5	17 Mar 1997 (17.03.97)	GB	23 Jun 1997 (23.06.97)

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Date of mailing (day/month/year) 26 June 1997 (26.06.97)	
Applicant's or agent's file reference PCT 393 1 CTH	**IMPORTANT NOTIFICATION**

International application No.	**International filing date** (day/month/year)	**Priority date** (day/month/year)
PCT/GB97/01426	23 May 1997 (23.05.97)	24 May 1996 (24.05.96)

Applicant

IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY AND MEDICINE et al

The applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to the following application(s):

Priority application No:	Priority date:	Priority country:	Date of receipt of priority document:
9610944.2	24 May 1996 (24.05.96)	GB	24 Jun 1997 (24.06.97)

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